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09/803,773	03/12/2001	Judah Z. Weinberger	56330-A/JPW/PJP	8786

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 06/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SS

**Office Action Summary**

Application No.

09/803,773

Applicant(s)

WEINBERGER, JUDAH Z.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Drawings***

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities:
- a. In the sentence on page 1, lines 6-8, the current status of the parent application should be provided.
  - b. On page 8, line 25, "adhesing" apparently should read --adhering--.
- Appropriate correction is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

4. Claim 5 is objected to because of the following informalities: in line 3, "adhesing" apparently should read --adhering--. Appropriate correction is required.

5. Claim 8 is objected to because of the following informalities: in line 7, "callapsible" apparently should read --collapsible--. Appropriate correction is required.

6. Claim 25 is objected to because of the following informalities: in line 6, --segment-- apparently should be inserted following "tube" in order to maintain consistent terminology for the limitation in the claim. Appropriate correction is required.

7. Claim 28 is objected to because of the following informalities: in line 9, --segment-- apparently should be inserted following "tube" in order to maintain consistent terminology for the limitation in the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-24 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 5, 8 and 14, the pronoun "its" renders the claims indefinite. One cannot be certain what "its" refers to.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is an additional method step in order to disclose that a radiation

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dose is actively being administered to the patient. The claim discloses that the balloon catheter has a tube segment including a radioactive material, but there is no indication that a radiation dose is being administered to the patient until the balloon catheter is removed "after a desired radiation dose has been achieved."

Regarding claims 29 and 30, the preamble of the claims is inconsistent with that of the corresponding independent claim 28. Claim 28 recites an apparatus. Claims 29 and 30 recite a tube segment. It is unclear whether claims 29 and 30 are further limiting the combination of elements that form the apparatus or merely the tube segment of the apparatus.

Claim 31 recites the limitation "the distal end of a tube" in line 5. There is insufficient antecedent basis for this limitation in the claim. The tube is not disclosed as having a distal end prior to this recitation.

### *Claim Rejections - 35 USC § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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11. Claims 1, 3-8, 10-14, 16, 17, 20 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. ('282). Fischell et al. teach a balloon catheter **40** for irradiation of arterial stenosis including an inflatable balloon **51** and a cylindrical, elastic radioactive source **52** both located coaxially at a distal end of the balloon catheter. The cylindrical radioactive source is a tube segment **52** formed of a mixture of radioactive material and non-radioactive material. The tube segment **52** can be an expandable and collapsible material, and is adhered to either the outer surface or the inner surface of the balloon **51**. The radioactive material is present in a predetermined dosage per surface area when the tube is in an unexpanded state, but that dosage changes as the tube **52** is expanded. A plurality of tube segments are provided having different sizes and doses so that a given tube segment can be selected according to a desired radiation dosage. In an alternative embodiment, the tube segment **73** is mounted to a shaft **12** of the catheter **60** inside of the balloon **72**. In operation, the balloon of the balloon catheter including the tube segment formed of a radioactive material is inserted into a luminal structure, is inflated with a gaseous media such as carbon dioxide, is deflated after a desired radiation dose has been achieved, and is finally removed from the luminal structure.

12. Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Columbo et al. Columbo et al. teach a cylindrical stent for treating a disease process in a luminal structure. The stent is a tubular segment and includes a radioactive material for producing radiation. The radiation dose varies along axial and longitudinal dimensions of the tube segment.

13. Claims 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hehrlein.

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Hehrlein teaches a balloon catheter **1** for eliminating vessel restrictions or stenoses; for inhibiting restenosis in arteries, veins or vessel implants; or for inhibiting the growth of tumors. The balloon catheter **1** includes a shaft and an inflatable balloon **2** having at least one radioactive nuclide species in or on the wall of the balloon **2**. A tube segment **4** is provided that is adapted to cover the balloon and to be moved longitudinally relative to the balloon to uncover the balloon to thereby respectively shield and unshield the radioactive material from the luminal structure when deployed. The tube segment **4** includes radioactive shielding material (col. 3, lines 3-5)

The subject matter of claims 31 and 32 was not disclosed in parent application Serial No. 09/271,063. Therefore, claims 31 and 32 are not awarded the benefit of the earlier filing date.

*Claim Rejections - 35 USC § 103*

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 2, 9, 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. ('282) in view of Hess ('168). Fischell et al. teach all of the limitations of the claims except that the radioactive material is in the form of a coating. It is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. Hess teaches a stent **74** which is coated with a radioactive material in order to assist in preventing restenosis of an artery. It would have

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been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Fischell et al. by coating a tubular segment with a radioactive material in view of the teachings of Hess.

16. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. ('282) in view of Waksman et al. Fischell et al. teach all of the limitations of the claims except that the tubular segment is sheathed in foil and can comprise a coil. Waksman et al. teach an apparatus for treating a desired area in the vascular system of a patient. The apparatus includes a balloon catheter **254** having a shaft **272** and an inflatable balloon **274**, and a tube segment **22** including radioactive material mounted on the shaft **272** inside of the balloon **274**. The tube segment **22** can be sheathed in foil and configured as a coil (Figure 11). It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to provide a radioactive tubular segment similar that of Fischell et al. with a foil sheath and a coil in view of the teachings of Waksman et al. in order to contain radioactive microparticles within the tubular segment.

17. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbo et al. in view of Hess ('466).

Columbo et al. teach a cylindrical stent for treating a disease process in a luminal structure. The stent is a tubular segment and includes a radioactive material for producing radiation. The radiation dose varies along axial and longitudinal dimensions of the tube segment.



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The stent is a balloon expandable stent (claim 15). Columbo et al. teach all of the limitations of the claims except that the apparatus further includes a balloon catheter.

Hess ('466) teaches an apparatus for restenosis treatment including a balloon catheter including a shaft **72** and an inflatable balloon **78** and a stent **74**.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a balloon catheter with a tubular stent similar to that of Columbo et al. in view of the teachings of Hess in order to deliver the stent to an area within an artery or vein for treatment.

### *Double Patenting*

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,200,256 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent.

Regarding independent claims 1, 8 and 14 of the instant application, all of the elements of the claims are recited in claim 11 of the patent. All of the aforementioned claims recite a tube segment including a radioactive material that is carried by a balloon catheter including a shaft and an inflatable balloon, where the tube segment is disposed over the balloon and is made of an expandable and collapsible material such that the shape of the tube segment is determined by the shape of the balloon. Claim 11 of the patent further recites that the tube segment is only radioactive at the portion that covers the balloon.

Claims 2, 9 and 15 of the instant application correspond to claim 8 of the patent. Claims 3, 10 and 16 of the instant application correspond to claim 9 of the patent. Claims 4, 11 and 17 of the instant application correspond to claim 10 of the patent. Claims 5 and 12 of the instant application correspond to claim 13 of the patent. Claim 6 of the instant application corresponds to claim 12 of the patent. Claim 7 of the instant application corresponds to claim 14 of the patent. Claim 13 of the instant application corresponds to claim 6 of the patent. Claim 18 of the instant application corresponds to claim 15 of the patent. Claim 19 of the instant application corresponds to claim 16 of the patent. Claim 20 of the instant application corresponds to claim 17 of the patent. Claim 21 of the instant application corresponds to claim 18 of the patent.

Regarding independent claim 22 of the instant application, all of the elements of the claim are recited in claim 22 of the patent. All of the aforementioned claims recite a method for treating a disease process in the vicinity of a luminal structure having similar method steps. Claim 22 of the patent differs from the claim of the instant application in that only a portion of the tube segment is provided with radioactive material.

Claim 23 of the instant application corresponds to claim 20 of the patent. Claim 24 of the instant application corresponds to claim 21 of the patent.

Regarding claims 24-30 of the instant application, all of the elements of the claims are recited in claim 1 of the patent. All of the aforementioned claims recite a tube segment that is carried by a balloon catheter having a shaft and an inflatable balloon, where the tube segment includes a radioactive material for administering a radiation dose which varies along a dimension of the tube segment. Claim 1 of the patent limits the dimension to an axial or longitudinal dimension as the tube of that claim is only radioactive at a distal end thereof.

Since the more specific patented claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

### *Conclusion*

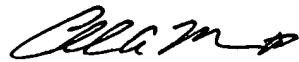
20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II  
Examiner  
Art Unit 3736



CAM

June 6, 2002